UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PROCTER & GAMBLE COMPANY,	:	
Plaintiff,	:	**No. 07 Civ. 8379 (RJS)**
vs.	:	**ECF Case**
ULTREO, INC.,	:	
Defendant.	:	

AFFIDAVIT OF AARON BIESBROCK IN SUPPORT OF PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

STATE OF OHIO)
: ss.:
COUNTY OF HAMILTON)

Aaron Biesbrock, being duly sworn, deposes and says as follows:

BACKGROUND

1. I am the Associate Director, Head of Global Oral Care Clinical Research at The Procter & Gamble Company ("P&G"). In this position, I am responsible for supervising all clinical testing that P&G globally sponsors related to oral care. My research group conducts between 75 and 100 clinical studies each year. I am responsible for ensuring that the study design has scientific merit, that the studies are conducted in accordance with the study protocol, and I oversee the analyses and interpretation of all P&G oral care clinical research.

2. I obtained my Bachelor of Science degree, in Biology, from North Georgia College in 1986. Following that, I enrolled in the Medical College of Georgia, where I received a Masters of Science in Oral Biology and a Doctorate in Dental Medicine in 1989. I

then proceeded to enroll in the State University of New York in Buffalo ("SUNY"), where I obtained my Ph.D. in Oral Biology in 1995.

3. Following my graduation from SUNY, I joined P&G as a research scientist in 1995. Since that time, I have held a number of research positions at P&G.

4. I am currently licensed by the state dental board of Ohio and have previously held a dental license in the state of Georgia. I am a practicing dentist, currently treating patients on a part-time basis in a dental group practice in Mason, Ohio. In the field of oral biology, I have published over a hundred manuscripts and abstracts, and made numerous presentations. I am a peer journal reviewer for the *American Journal of Dentistry* and the *Journal of Periodontology*. A copy of my curriculum vitae is attached as Exhibit A.

5. I submit this affidavit in support of P&G's Motion for a Preliminary Injunction and Expedited Discovery.

GENERAL BACKGROUND ON TOOTHBRUSHES

6. There are several types of toothbrushes available on the market today. The two basic types of toothbrushes are manual and power (including battery) toothbrushes. Power toothbrushes include those where the bristles rotate and oscillate, as well as those where the bristles purport to move at "sonic" speeds.

7. Plaque is a sticky substance that is made up of a bacterial biofilm, which can be harmful if left on the teeth. Plaque must be removed on a regular basis in order for teeth and gums to remain healthy. To date, the only clinically proven way to remove plaque from the teeth with a toothbrush is by mechanically disrupting the plaque found on the teeth. A toothbrush mechanically removes plaque when the bristles of the brush move along the surface of the tooth to disrupt the plaque.

8. Ultreo is marketing a new type of power toothbrush (called "Ultreo") that combines sonic bristle motion with an ultrasound wave generator. Like the existing sonic toothbrushes, its bristles move at sonic speeds. However, the Ultreo toothbrush purports to be unique, in that it also projects ultrasonic energy from the toothbrush head. I understand that Ultreo claims that the use of ultrasound results in the removal of plaque. I also understand that Ultreo advertises that its bristle action creates bubbles that are activated by nearly 4 million cycles of ultrasound energy.

ULTREO'S *IN VITRO* STUDY

9. Ultreo conducted an *in vitro* study to determine whether the ultrasound feature of the Ultreo toothbrush removed plaque in areas where the bristles did not make contact. For purposes of this study, a single type of bacteria found in plaque was grown on hydroxyapatite discs and frosted glass slides. Hydroxyapatite discs are similar to tooth enamel and were positioned 3 millimeters from the ultrasound waveguide. The frosted glass slides contained grooves 0.2 millimeters wide and 0.75 millimeters deep. The surfaces of the grooved slides were directly brushed with the Ultreo bristle tips, while the ultrasound waveguide was operating. I understand that this *in vitro* study was conducted in a submerged environment, containing a dentrifice slurry (which is essentially toothpaste dissolved in water).

10. According to abstracts made available by Ultreo in connection with this *in vitro* study, Ultreo removed significantly more bacteria from the hydroxyapatite discs without bristle contact than other power toothbrushes. Ultreo also claims that the study demonstrated that Ultreo's combined sonic and ultrasonic activity removed the bacteria from the grooved glass slides. Ultreo has not made the protocol or data available for this study.

11. To the best of my knowledge, Ultreo has not conducted an *in vivo* study that demonstrates the effectiveness of the ultrasound waveguide in removing plaque in areas where the bristles do not come into contact with the teeth.

IN VITRO STUDIES CANNOT BE REPLICATED IN THE MOUTH

12. As with the Ultreo *in vitro* study, there are a number of *in vitro* studies that have reported that sonic toothbrushes remove plaque by dynamic fluid motion caused by the sonic waves and sonic bristle action and without the aid of mechanical disruption by the toothbrush bristles.[1] In diametric contrast to these *in vitro* studies, multiple clinical studies have demonstrated that power rotation-oscillation toothbrushes remove more plaque than sonic toothbrushes, including in the difficult-to-reach areas.[2] These clinical observations are further supported by the Cochrane Collaboration systematic review that reported that the body of

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[1] C.K. Hope and M. Wilson, "Effects of dynamic fluid activity from an electric toothbrush on in vitro oral biofilms," *Journal of Clinical Periodontology* (July 2003) at 624-629; Heather Adams, Matthew T. Winston, Joanna Heersink, Kelli Buckingham-Meyer, J. William Costerton and Paul Stoodley, "Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing," *American Journal of Dentistry*, Vol. 15, Special Issue (Nov. 2002) at 12B-17B; Clark M. Stanford, Ruparee Srikantha and Christine D. Wu, "Efficacy of the Sonicare® Toothbrush Fluid Dynamic Action on Removal of Human Supragingival Plaque," *The Journal of Clinical Dentistry*, Vol. VIII, No. 1 (1997) at 10-14; Christine D. Wu-Yuan, Richard D. Anderson and Christopher McInnes, "Ability of the Sonicare® Electronic Toothbrush to Generate Dynamic Fluid Activity that Removes Bacteria," *The Journal of Clinical Dentistry*, Vol. V, No. 3 (1994) at 89-93. Copies of these articles are attached as Exhibits B-E.

[2] Aaron R. Biesbrock, Robert D. Bartizek, Patricia A. Walters, Paul R. Warren, MaryAnn Cugini and C.R. Goyal, "Clinical Evaluations of Plaque Removal Efficacy: An Advanced Oscillating-Rotating Power Toothbrush versus a Sonic Toothbrush," *The Journal of Clinical Dentistry* (2007) (in Press); N. Sharma, J. Qaquish, M. Cugini, M.C. Thompson and P.R. Warren, "Plaque removal of three power toothbrushes," *Journal of Dental Research* (2006) Abstract 2054; J. Strate, M.A. Cugini, P.R. Warren, J.G. Qaquish, H.J. Galustians, N.C. Sharma, "A comparison of the plaque removal efficacy of two power toothbrushes: Oral-B Professional care series versus Sonicare Elite," *International Dental Journal* (2005) at 151-156; N.A. Rosema, M.F. Timmerman, M. Piscaer, J. Strate, P.R. Warren, U. Van der Velden and G.A. Van der Weijden, "An oscillating/pulsating electric toothbrush versus a high frequency electric toothbrush in the treatment of gingivitis," *Journal of Dentistry*, Vol. 33, Supp. 1 (2005) at 29-36; N.C. Sharma, C.R. Goyal, J.G. Qaquish, M.A. Cugini, M.C. Thompson and P.R. Warren, "Single use plaque removal efficacy of three power toothbrushes," *Journal of Dentistry*, Vol. 33, Supp. 1 (2005) at 11-15. Copies of these articles are attached as Exhibits F-J.

clinical evidence supports that only rotation-oscillation power toothbrushes were consistently superior to manual toothbrushes for plaque removal.[3] The Cochrane Collaboration is an independent, non-profit international organization.

13. There are a number of reasons that explain why clinical results are routinely different than the results of *in vitro* studies in connection with the removal of plaque. As a general matter, *in vitro* studies have a number of components that are inconsistent with the clinical environment of the mouth.

14. Often the bacteria that is grown for use in the *in vitro* study does not mimic the complex plaque bacteria that is found in the human mouth (and on teeth) that contains 30 to 300 types of bacteria. Not only is there a multitude of types of bacteria in plaque, but studies have shown that the various types of plaque bacteria found in the mouth interact with each other. It is extremely difficult to model naturally-occurring plaque bacteria. All attempts are compromises between the realities of the *in vivo* conditions of a person's mouth and the need for simple and controllable bacteria in order to get meaningful results from the *in vitro* study. While there are ways to create plaque bacteria *in vitro* that have more characteristics of the plaque bacteria found naturally, these methods may not be practical for a given *in vitro* study.[4]

15. The dilemma is that in order for an *in vitro* study to explain and predict plaque behavior accurately, the bacteria used for the *in vitro* study must be realistic. The

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[3] M. Heanue, S.A. Deacon, C. Deery, P.G. Robinson, A.D. Walmsley, H.V. Worthington, W.V. Shaw, "Manual versus powered toothbrushing for oral health," Wiley Pub. (2004). A copy of this article is attached as Exhibit K.

[4] Paul E. Kolenbrander, Roxanna N. Anderson, David S. Blehert, Paul G. Egland, Jamie S. Foster and Robert J. Palmer, "Communication among Oral Bacteria," *Microbiology and Molecular Biology Reviews*, vol. 66, no. 3 (Sept. 2002) at 486-505; C.H. Sissons, "Artificial Dental Plaque Biofilm Model Systems," *Advanced Dental Research* (Apr. 1997) at 110-126. Copies of these articles are attached as Exhibits L and M.

majority of *in vitro* studies, though, use only a single type of bacteria. A single bacteria lacks all of the indicia of natural plaque, which is characterized by its complex nature. Consequently, the ability to predict how naturally-occurring plaque will react based upon knowledge gleaned from a test involving a single type of bacteria is extremely limited.

16. The type of plaque bacteria is not the only difference between *in vitro* and *in vivo* studies. The presence of salivary protein in the mouth may also impact the effectiveness of plaque-removal efforts. In a study comparing the *in vitro* and *in vivo* effects of certain antibacterial agents, no correlation was found between the *in vitro* and *in vivo* effects.[5] In this study, it was clear that something other than antibacterial properties of the tested substances had to impact plaque removal.

17. Yet another reason why *in vitro* studies are not accurate predictors of *in vivo* plaque removal for sonic toothbrushes is because most of these *in vitro* studies are conducted with the toothbrush head fully submerged in water (or a similar liquid). Yet an individual's mouth is never completely filled with saliva. Instead, the volume of saliva found in the mouth at any given time due to gravity and the swallow reflex, is 1.07 milliliters, plus or minus 0.39 milliliters.[6] Moreover, in some *in vitro* studies, the surface that is intended to represent teeth is often not an acceptable substitute. Finally, some *in vitro* studies fail to use toothpaste, which can have an impact on both bacteria and plaque.

18. *In vitro* studies, while they are not necessarily accurate predictors of what will occur in the mouth, do serve a useful purpose in the scientific arena. *In vitro* models are

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[5] Per Gjermo, Kirsten Lyche Baastad and Gunnar Rölla, "The plaque-inhibiting capacity of 11 antibacterial compounds," *Journal of Clinical Periodontology*, Vol. 5 (1970) at 102-109. A copy of this article is attached as Exhibit N.

[6] F. Lagerlöf and C. Dawes, "The Volume of Saliva in the Mouth Before and After Swallowing," *Journal of Dental Research* (May 1984) at 618-621. A copy of this article is attached as Exhibit O.

excellent for the creation of hypotheses and exploring the mechanism of action. However, they are only the initial step in a comprehensive analysis of an issue before confirming the conclusion clinically.[7]

P&G'S *IN VIVO* STUDY

19. In light of the limitations of *in vitro* studies in connection with claims of plaque removal, P&G decided to conduct an *in vivo* study to evaluate the effectiveness of plaque removal of the Ultreo toothbrush. A copy of the study protocol and results are attached hereto as Exhibit P.

20. Thirty-one adults participated in the study. The study was a 4-treatment, 8-period crossover clinical study, which means that each of the subjects used each of the 4 different treatments twice. The four treatments were:

- brushing with the Ultreo toothbrush for two minutes in accordance with the manufacturer's directions;
- brushing with the Ultreo toothbrush for two minutes with the power turned off, as if it were a manual toothbrush;
- placing the Ultreo toothbrush, with the power turned on, approximately 3 millimeters from the surface of the teeth, so that the bristles do not come into contact with the teeth for two minutes;[8] and
- swishing for one minute with a dentifrice slurry (comprised of 1 part toothpaste to 3 parts water) and did not use a toothbrush.

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[7] *See* N.C. Sharma, C.R. Goyal, J.G. Qaquish, M.A. Cugini, M.C. Thompson, P.R. Warren, "Single use plaque removal efficacy of three power toothbrushes," *Journal of Dentistry* 2005; 33 (Supp. 1). A copy of this article is attached as Exhibit J.

[8] A trained dental hygienist held the Ultreo toothbrush head using the tips of the orange side bristles to touch the incisal tooth edge and marginal gingival as a guide. The distance of the waveguide from the tooth surface was determined to be 3 millimeters using the orange side bristles as a guide. The hygienist was trained in advance of the study to follow these instructions when moving the toothbrush head through the mouth.

Subjects were randomly assigned to one of sixteen treatment sequences. Each subject used each treatment twice during the course of the study.

21. These treatment groups were selected in an effort to replicate Ultreo's *in vitro* study, in particular, holding the Ultreo toothbrush 3 millimeters from the surface of the teeth.

22. At the first visit, the subjects were given a tube of Crest Cavity Protection Gel toothpaste and an Ultreo toothbrush to be used at home for approximately seven days. Subjects received brushing instructions (per manufacturer's instructions) and brushed for 2 minutes at the site under supervision for their first brushing. Subjects were instructed to use the new products in place of their normal products until 48 hours prior to their second visit, to brush twice daily according to instructions provided, and to bring the new products with them when they return for the second visit. Subjects were also instructed to use their normal at-home toothbrush instead of Crest Cavity Protection Gel toothpaste for the period between 48 hours and 24 hours prior to the second visit. The subjects were asked to refrain from all oral hygiene procedures for 23-25 hours prior to their scheduled second visits. In addition, the subjects were asked to refrain from eating, drinking, chewing gum and smoking for 4 hours prior to their appointment time.

23. The subjects returned to the clinic for their second visits. Upon arrival, each subject was evaluated to determine whether it was appropriate for him or her to remain in the study. The subjects swished their mouth with red dye for one minute, in order to highlight the plaque on the teeth. At this time, an experienced plaque examiner conducted a plaque examination of every tooth (excluding third molars, crowns and restorations) using the Turesky Modified Quigley-Hein Plaque Index.

24. The Turesky Modified Quigley-Hein Plaque Index measures plaque found on teeth and is a well-recognized method to measure plaque removal. The Turesky Modified Quigley-Hein Plaque Index is recognized by the American Dental Association as a well-accepted plaque index.[9]

25. To measure plaque in accordance with the Turesky Modified Quigley-Hein Plaque Index, the examiner looks at the surface of the tooth and categorizes the amount of plaque based upon the following scale:

0 = No plaque;

1 = Separate flecks of plaque at the cervical margin of the tooth;

2 = A thin, continuous band of plaque (up to 1 millimeter) at the cervical margin of the tooth;

3 = A band of plaque wider than 1 millimeter, but covering less than one-third of the crown of the tooth;

4 = Plaque covering at least one-third, but less than two-thirds of the crown of the tooth;

5 = Plaque covering two-thirds or more of the side of the crown of the tooth.

26. The subjects then performed their assigned treatment regimen. For those subjects using the Ultreo toothbrush, a pea-sized amount of Crest Cavity Protection Gel toothpaste was applied to the brush by the site staff. All treatment regimens were performed under observation.

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[9] *See* ADA Acceptance Program Guidelines for Toothbrushes (2006), a copy of which is attached as Exhibit Q. The other common index to measure plaque removal is the Rustogi Modified Navy Plaque Index. Despite the differences between these indices, studies have demonstrated that there both indices demonstrate sufficient sensitivity to differentiate toothbrush efficacy. *See* MaryAnn Cugini, Maureen Thompson, Paul R. Warren, "Correlations Between Two Plaque Indices in Assessment of Toothbrush Effectiveness," *The Journal of Contemporary Dental Practice*, vol. 7, no. 5 (Nov. 1, 2006). A copy of this article is attached as Exhibit R.

27. After completing the assigned treatment regimen, the subjects swished with the red dye again for one minute and then received a second plaque examination. The plaque scores were averaged on a per-subject basis so that each subject had a single whole-mouth average score at baseline and another whole-mouth average score following their treatment regimen. The difference (baseline minus post-regimen) in average scores was calculated for each subject.

28. This process was repeated for a total of eight visits for each subject.

29. Baseline plaque scores averaged between 2.181 and 2.216 prior to using each of the four treatment regimens. There was no statistical difference for the baseline scores between the regimens.

30. Adjusted mean plaque removal scores were calculated for each technique by subtracting the plaque score after the technique from the baseline plaque score. The results of this analysis revealed that the removal of plaque was best by the Ultreo toothbrush used as a manual, followed by the Ultreo toothbrush used in accordance with the manufacturer's instructions. There was no statistically significant difference between a dental hygienist holding the Ultreo toothbrush approximately 3 mm from tooth surfaces and swishing a toothpaste slurry around the mouth without brushing.

31. The overall results for the P&G clinical study are as follows:

Treatment	**Baseline Scores**	**Mean Plaque Removal Scores**
Swishing with a dentifrice slurry	2.207	0.052
Dental hygienist holding the Ultreo toothbrush approximately 3 millimeters from tooth surfaces	2.216	0.058
Brushing with the Ultreo toothbrush according to manufacturer's instructions	2.181	0.536
Ultreo toothbrush (power turned off) used like a manual toothbrush	2.202	0.666

32. The difference between the Ultreo toothbrush held approximately 3 mm from tooth surfaces and swishing with a dentifrice slurry was not statistically significant ($p=0.808$).

33. Brushing with the Ultreo toothbrush like a manual toothbrush (power turned off) was statistically superior to using the Ultreo pursuant to manufacturer's instructions ($p<0.001$). Ultreo used like a manual toothbrush had an adjusted mean plaque removal score that was 12.4% greater than that for Ultreo used per manufacturer's instructions.

34. Specific analyses were also conducted on various surfaces of the teeth and certain teeth. Specifically, analyses were done of the surfaces of the teeth that face the cheek (called the "buccal surfaces"), surfaces of the teeth that face the tongue (called the "lingual surfaces"), the maxillary teeth and the mandibular teeth. For each, there were no statistical differences among the groups for baseline plaque scores. In all sub-groups, there was no statistical difference between swishing and the Ultreo toothbrush being held approximately 3 millimeters from tooth surfaces. Similarly, in all sub-groups, the use of the Ultreo toothbrush with the power turned off was superior to using the Ultreo toothbrush, with the power turned on and in accordance with the manufacturer's instructions.

35. In contrast to Ultreo's data from its *in vitro* studies, the results of this study demonstrate that the Ultreo toothbrush does not remove any more plaque than simply swishing toothpaste around one's mouth, unless the toothbrush bristles contact the tooth surface. The plaque reduction observed in the no brushing group was virtually identical and not statistically significantly different than the plaque removal observed in group where the Ultreo toothbrush was held 3 millimeters from the teeth. Indeed, both groups exhibited a tiny reduction in plaque, but that is likely to be attributable to the detergent effect of the toothpaste introduced into the mouth or the subjects swishing with the disclosing agent and water after treatment. The absence of a clinical plaque effect beyond the bristle cleaning is further supported by Ultreo removing statistically significantly more plaque when turned off and used like a manual toothbrush than when used with the power turned on. These findings were consistently observed across all subset analyses. Collectively, the data fails to support that Ultreo removes plaque by any means other than mechanical and physical contact of the bristles with the teeth.

36. Additionally, I understand that Philips, the maker of the Sonicare® toothbrush, also has conducted its own *in vivo* clinical study to determine the plaque removal of Sonicare FlexCare, Ultreo and Ultreo with the ultrasound function disabled. As in the P&G study, the subjects had an assessment of plaque before and after brushing in accordance with the Turesky modified Quigley-Hein Plaque Index. According to the abstract available on the Sonicare website, the study revealed that there was no significant difference in plaque removal ($p=0.52$) between the Ultreo with ultrasound function enabled or disabled. A true and correct copy of the abstract of this study, as found on www.sonicare.com, is attached as Exhibit S.

37. Given the artificial nature of the *in vitro* study evaluating the Ultreo toothbrush, it is not surprising that it is a poor predictor of the clinical outcome. In the Ultreo *in vitro* study, only a single form of bacteria was formed over a 48-hour period on hydroxyapatite

chips or glass slides. This is in contrast to the oral cavity where the enamel tooth surfaces are coated with saliva that creates complex plaque development, involving 30 to 300 bacterial species. The use of frosted glass slides in the Ultreo study does not replicate teeth surfaces. Additionally, I believe that the Ultreo *in vitro* study was conducted in a submerged aqueous environment, which also is inconsistent with the oral cavity environment, since there is actually very little fluid found in an individual's mouth at any given time.

FOUR MILLION CYCLES

38. It is unclear what the support is for Ultreo's claim that the ultrasound in its toothbrush operates at "nearly 4 million cycles." According to Ultreo's reported data, the ultrasound emitted from the Ultreo toothbrush cycles at 324,000 hertz, which is obviously well short of 4 million cycles. Attached as Exhibit T is a copy of "Ultrasound Technology: Transitioning into Oral Care and Beyond," written by Gayle B. McCombs.

39. Assuming that Ultreo cycles at 324,000 hertz per burst, as noted in its own reported data, that means it will take over two minutes for it to reach 4 million cycles. A burst is 15.2 milliseconds. That means there are 4,924.8 cycles in a burst. There are 6.5 bursts in a second, so that calculates to 32,011.2 cycles per second. Therefore, the number of cycles in a minute is 1,920,672. Typically, ultrasound cycles are reported in units of cycles per second (hertz) rather than cycles per minute.

Aaron Biesbrock

Sworn to before me this

10 day of October, 2007

Julie A. Gibson

Notary Public

JULIE A. GIBSON
Attorney At Law
Notary Public, State of Ohio
My commission has no expiration date
Sec. 147.03 R.C.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing was served electronically by the Court's ECF system pursuant to the rules of this court.

Dated December 17, 2007

s/ Laura W. Sawyer
Laura W. Sawyer